

Remarks

The Office Action dated February 2, 2010 has been received and reviewed. Claims 1, 11-14, 17, 19, 21, 23, and 25 having been amended herein, claims 4, 16, 18, 20, 22, and 24 having been cancelled herein, without prejudice, claims 5 and 6 having been previously cancelled, and claims 26-34 having been added herein, the pending claims are claims 1-3, 7-15, 17, 19, 21, 23, and 25-34. Reconsideration and withdrawal of the rejections are respectfully requested.

Claims 1 and 11-14 have been amended to recite a range of amounts of a compound having an SO₂-NH group. Support for the amendments to claims 1 and 11-14 may be found throughout Applicants' specification and specifically at, for example, page 9, lines 21-23.

Support for new claims 26 and 27 may be found throughout Applicants' specification and specifically at, for example, page 8, lines 4-14.

Support for new claims 28 and 29 may be found throughout Applicants' specification and specifically at, for example, page 9, lines 12-20 and the claims. Support for new claims 30-34 may be found throughout Applicants' specification and specifically at, for example, page 8, line 23 to page 9, line 11 and the claims.

Entry and consideration of the claim amendments and new claims are requested.

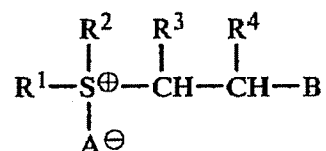
The 35 U.S.C. §112, first paragraph, Rejections

The Examiner rejected claims 17, 19, 21, 23, and 25 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner alleged that "[i]t would require undue experimentation to determine all of the groups which are encompassed by 'substituted' and how to attach these groups to the claimed compound." (Office Action dated February 2, 2010, page 2.) Applicants traverse this rejection.

"The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without

undue experimentation" M.P.E.P §2164.01 (quoting *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988)). Further, "[t]he fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." M.P.E.P §2164.01 (citing *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd sub nom.*, *Mass. Inst. of Tech. v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985)).

Applicants submit that the Examiner has failed to articulate any analysis of the *Wands* factors (see *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)) in the rationale underlying the present rejection. For at least this reason, the rejection must fail. Applicants have provided sufficient guidance such that one of ordinary skill in the art is able to make and use the claimed invention. For example, at page 10, lines 12-13 of the present specification, U.S. Patent No. 4,167,618 is incorporated therein by reference for the disclosure of exemplary substituted alkyl sulfonium salts. For example, the abstract of U.S. Patent No. 4,167,618 discloses the following substituted alkyl sulfonium salts



where

R¹ is an alkyl radical of 1 to 18 C atoms,

R² is an alkyl radical of 1 to 18 C atoms or a phenyl alkyl radical of 7 to 18 C atoms, wherein said alkyl radicals may contain an ester group and/or ether group, **R³** and **R⁴** are hydrogen, an alkyl radical of 1 to 18 C atoms, and/or an aryl radical which can be substituted with a chloro, nitro or alkoxy group, whereby the alkyl radicals of **R³** and **R⁴** together or in combination with **B** can form a cycloaliphatic or heterocyclic ring, **B** is an electron attracting radical, and **A[⊖]** is a non-nucleophilic anion.

Further, U.S. Patent No. 4,167,618 discloses over 70 specific examples of substituted alkyl sulfonium salts in the examples. It should be understood, however, that the present invention is not limited to those specific substituted alkyl sulfonium salts.

Further, *Wands* factors include, *inter alia*, (1) the nature of the invention; (2) the state of the prior art; and (3) the level of one or ordinary skill. Applicants assert, with respect to determining the groups encompassed by "substituted," such a determination is well-known and relatively routine in the art; thus, even though such experimentation may be complex or arduous, it is not "undue."

In view of the above comments, Applicants assert that the rejected claims are fully enabled. Reconsideration and withdrawal of the rejection of claims 17, 19, 21, 23, and 25 under 35 U.S.C. §112, first paragraph, for lack of enablement are respectfully requested.

The 35 U.S.C. §103 Rejections

The Examiner rejected claims 1-4 and 7-25 under 35 U.S.C. §103(a) as being unpatentable over Eckhardt et al. (U.S. Application No. 2003/0153726 A1) in view of Schmitt et al. (U.S. Patent No. 4,167,618). The Examiner rejected claims 1-4, 7-11, 13-16, 18, 22, and 24 under 35 U.S.C. §103(a) as being unpatentable over Zech et al. (U.S. Patent No. 6,894,144 or WO 01/17483). The Examiner also rejected claims 1-4, 7-11, 13-19, and 22-25 under 35 U.S.C. §103(a) as being unpatentable over Zech et al. in view of Schmitt et al. Claims 4, 16, 18, 20, 22, and 24 have been cancelled, rendering the rejections of these claims moot. Regarding all other rejected claims, Applicants traverse the rejections.

Applicants respectfully point out that despite the ruling of *KSR Int'l Co. v. Teleflex, Inc.* (82 USPQ2d 1385 (2007)), a rejection made on the basis of obviousness still requires that all of the claim limitations be taught by the asserted modification or combination of cited references ("To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed

invention to have been obvious in light of the teachings of the references.” M.P.E.P. §706.02(j), 8th Ed., Rev. 6 (Sept. 2007), page 700-48, *citing*, *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985)). Applicants assert that in each of the rejections made by the Examiner in the Office Action dated February 2, 2010, the Examiner committed clear error by failing to consider the cited documents as a whole and, thus, by failing to acknowledge that mere overlap of the amounts of a compound does not establish a *prima facie* case of obviousness, especially when that compound is not explicitly disclosed or suggested by the cited documents.

A. Claims 1-3, 7-15, 17, 19, 21, 23, and 25 are not unpatentable under 35 U.S.C. §103(a) over Eckhardt et al. (U.S. Application No. 2003/0153726 A1) in view of Schmitt et al. (U.S. Patent No. 4,167,618).

Without acquiescing to the Examiner’s rejection or supporting allegations and merely to expedite prosecution of the present application, claims 1 and 11-14 have been amended and now recite a dental composition (e.g., claim 1), a kit (e.g., claims 11 and 12), a method of producing a dental composition (e.g., claim 13), and a method for enhancing the setting speed of a dental composition (e.g., claim 14), each of which include, among other things, a compound having an SO₂-NH group (e.g., SO₂-NHR or SO₂-NH₂), wherein the compound is present in an amount of about 0.01% by weight to about 6.0% by weight.

Insofar as this rejection applies to the presently pending claims, it is respectfully traversed.

In the present rejection, the Examiner relied on Eckhardt et al.’s disclosure of constituents of catalyst components that include 0 to 95 weight percent of at least one inert diluent (paragraph [0033]). The Examiner has apparently equated Eckhardt et al.’s inert diluent to the presently recited compound having an SO₂-NH group and alleged that Eckhardt et al.’s amounts of the diluents overlaps the instant amounts (“about 0.01% by weight to about 6.0% by weight”) of the compound having an SO₂-NH group.

“[I]t is not uncommon that a ‘species’ may be patentable, that is, satisfy sections 101-103, notwithstanding a prior art ‘genus.’” *In re Ornitz*, 376 F.2d 330, 336, 153 USPQ 453, 458 (CCPA 1967). “The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness.” M.P.E.P. §2144.08 (citing *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)). Furthermore, “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” M.P.E.P. §2141.02 (citing *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)) (emphasis in original).

Applicants submit that the Examiner committed clear error by failing to consider Eckhardt et al. as a whole and, thus, by failing to acknowledge that mere overlap of the amounts of a compound does not establish a *prima facie* case of obviousness, especially when that compound is not explicitly disclosed or suggested by Eckhardt et al.

“The *KSR* Court recognized that ‘[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.’ *KSR*, 127 S. Ct. at 1732.” *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 1739 (2008) (emphasis added). Applicants submit that what Eckhardt et al. disclose “clearly is not the easily traversed, small and finite number of alternatives that *KSR* suggested might support an inference of obviousness.” See *Ortho-McNeil Pharm. Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008).

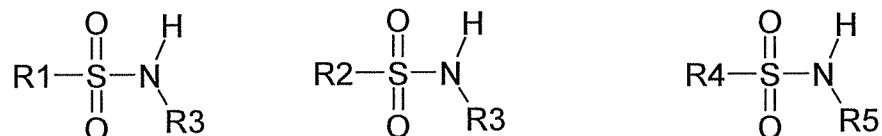
For example, from the very broad range of concentrations (0 to 95 weight percent, preferably 0 to 70 weight percent; paragraph [0033]) of inert diluent disclosed by Eckhardt et al., one of skill in the art would be required to select a relatively small concentration in a relatively narrow range (“about 0.01% by weight to about 6.0% by weight”) to arrive at the presently claimed concentration. Applicants’ recited range of weight percentage is a very small fraction of

the range disclosed in Eckhardt et al. Further, Eckhardt et al. provide no motivation to select an amount within the recited concentration range (about 0.1% by weight to about 6.0% by weight).

In addition to a selection of the presently recited amounts of the compound having an SO₂-NH group, Applicants submit that one of ordinary skill in the art must make a number of other selections to arrive at the presently claimed dental compositions, kits, and methods. Thus, the Examiner has not established a *prima facie* case of obviousness of the present claims over Eckhardt et al.

As discussed hereinbelow and in Applicants' remarks at pages 11-18 of Applicants' Amendment and Response submitted December 14, 2009, incorporated herein by reference, Applicants submit that Eckhardt et al. do not disclose or suggest the presently recited compound having an SO₂-NH group. Thus, the alleged overlap in the amounts of the recited compound having an SO₂-NH group and Eckhardt et al.'s inert diluent is irrelevant. Thus, the Examiner's reliance thereon in support of the present obviousness rejection is clear error.

As currently claimed, each of the independent claims incorporates a compound having an SO₂-NH group, wherein the compound is represented by at least one of the following formulas:



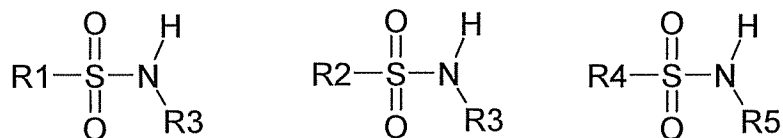
wherein R1-R5 are as recited in the claims and wherein the compound is present in an amount of about 0.01% by weight to about 6.0% by weight. Eckhardt et al. do not disclose a dental composition (or kit or method) including about 0.01% by weight to about 6.0% by weight of an SO₂-NH group-containing component as recited in the present claims.

Eckhardt et al. also fail to specify the amides which might be used as their so-called inert diluents. Also, there is no disclosure in Eckhardt et al. that the amides have to include an SO₂-NH group, as presently claimed. Eckhardt et al.'s phrase "amides of alkylsulphonic acid and arylsulphonic acids" (paragraph [0049]) does not comprise only amides having an SO₂-NHR

group (as presently claimed) or an SO₂-NH₂ group (as presently claimed), but also amides comprising an SO₂-NR₂ group (not presently claimed), wherein R is different from H.

Eckhardt et al. are totally silent regarding whether the inert diluent is a compound having a SO₂-NH group. In evaluating lack of disclosure regarding an obviousness rejection, the Court of Customs and Patent Appeals stated that “[s]ilence in a reference is hardly a proper substitute for an adequate disclosure of facts from which a conclusion of obviousness may justifiably follow.” *In re Burt and Walter*, 148 U.S.P.Q. 548, 553 (C.C.P.A. 1966).

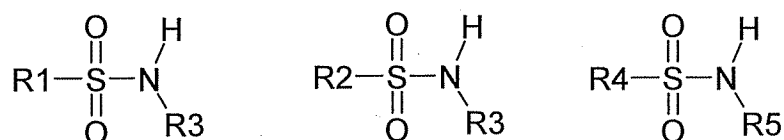
Thus, in order to arrive at the claimed subject matter, the person skilled in the art has to make the following selections: (1) identify from the group of possible compounds suggested as inert diluents the esters or amides of alkylsulfonic acids and arylsulfonic acids; (2) select the amides and not the esters of said acids; (3) select the compounds represented by at least one of the following formulas:



and (4) select each of groups R1-R5 as presently claimed (e.g., wherein R1 is a moiety selected from the group consisting of C₁-C₂₂ alkyl, C₂-C₂₂ alkenyl, C₂-C₂₂ alkynyl, C₇-C₂₂ arylalkyl and C₃-C₂₂ cycloalkyl, wherein one or more hydrogen atoms of the moiety may be replaced by Cl or F and/or up to five carbon atoms may be replaced by atoms or group of atoms selected from O, CO, N, and S, R2 is a moiety selected from the group consisting of C₆-C₁₈ aryl, C₇-C₂₂ alkylaryl, C₂-C₂₂ cycloalkylaryl, C₇-C₂₂ alkenylaryl and C₇-C₂₂ alkynylaryl, wherein one or more hydrogen atoms of the moiety may be replaced by Cl or F and up to five carbon atoms may be replaced by atoms or group of atoms selected from O, CO, N, and S, R3 is H, R1, or R2, R4 is R1 or R2, and R5 is a chemical linkage to a polymer).

Even further, Applicants' Representatives have not located and the Examiner has not identified any blaze marks in the cited documents that would lead one of skill in the art down a path to select all of the subject matter of the present claims. Thus, Applicants request that the

Examiner point to the blaze marks in the cited documents, either explicit or implicit, or anywhere in the general knowledge of one of skill in the art, that would lead one of skill in the art down a path to select, for example, a dental composition (or kit or method) that includes a compound having an SO₂-NH group, wherein the compound is represented by at least one of the following formulas:



wherein R1-R5 are as defined in the claims and wherein the compound having an SO₂-NH group is present in an amount of about 0.01% by weight to about 6.0% by weight (e.g., claim 1).

Applicants have found that selecting particular amounts of a compound having an SO₂-NH group provides advantages for the presently claimed dental compositions (or kits or methods). In a dental setting, it is not only desired to have a dental composition that hardens to a particular hardness, but it is also frequently desired to enhance setting speed. That is, early setting of the dental composition is frequently desired to reduce the time required for a dental procedure, thereby enhancing the patient's experience. Applicants have found that by selecting, for example, the recited amounts of a compound having an SO₂-NH group of "about 0.01% by weight to about 6.0% by weight" (e.g., amended claims 1 and 11-14), the setting speed can be enhanced. In particular, dental compositions having increased 6-, 8-, and 10-minute Shore A Hardnesses provide a significant advantage over alternative compositions, even if the ultimate Shore A Hardnesses (e.g., measured at 15 or more minutes) may be similar.

Such advantage obtained by selecting the recited amounts of the recited compound having an SO₂-NH group is not disclosed or suggested in Eckhardt et al.

By using the particular recited substances, Applicants have observed that the speed of set can be improved (that is, providing a dental composition with a shorter working time).

Experimental evidence of this effect (showing that sulfonamides with an SO₂-NRR' (R = alkyl, R' = alkyl) group do not accelerate the speed of cure in the same manner as sulfonamides with an

SO₂-NHR group, as shown in the Specification at Table 6, Entry 13, or sulfonamides with an SO₂-NH₂ group, as shown in the Specification at Table 6, Entry 14) was submitted in the Declaration of Dr. Thomas Klettke on July 14, 2009.

Applicants note that the speed of set varies from compound to compound. Where an early high Shore Hardness A is desired, Applicants have found that the compound used in Entry 15 (SO₂-NR₂) is less effective than, for example, the compounds in Entry 13 (SO₂-NH₂) and Entry 14 (SO₂-NHR), as is evident in the following table.

Entry	Compound	Shore A Hardness after 6 min	Shore A Hardness after 8 min	Shore A Hardness after 10 min
15	SO ₂ -NR ₂	23	33	37
14	SO ₂ -NH ₂	33	40	42
13	SO ₂ -NHR	30	37	42

(See Applicants' specification at pages 19 and 20.)

The Examiner alleged that the scope of the claims is broader than the showing in the Declaration of Dr. Thomas Klettke. (Office Action dated September 25, 2009, page 3.)

Although this is true, the experimental data in the Declaration establish that Eckhardt et al.'s mere disclosure of the phrase, "amides of alkylsulphonic acid and arylsulphonic acids are used as inert diluent" (emphasis added), does not necessarily disclose or suggest the subject matter of the present claims. Applicants submit that the dental compositions (and kits and methods) of the present claims offer enhanced setting speeds and that Eckhardt et al. fail to offer any guidance to one of skill in the art to select the presently recited components and form a composition or kit therewith.

While the Examiner appeared to focus on the Shore A Hardnesses of Entries 13-15 after 15 minutes (Office Action dated February 2, 2010, pages 3-4), Applicants submit that the Examiner has failed to properly consider the evidence submitted by Applicants traversing the

present rejections; namely, early setting (e.g., increased Shore A Hardness values at 6, 8, and 10 minutes) of the presently claimed dental compositions (and kits and methods).

Applicants respectfully remind the Examiner that “[e]vidence traversing rejections . . . must be considered by the examiner whenever present.” M.P.E.P. §716.01.

Applicants are unclear as to the Examiner’s intent at page 4 of the Office Action dated February 2, 2010, where the Examiner noted that all of the simplest form of the compound (such as having SO₂-NH₂, SO₂-NHR, or SO₂-NR₂) yielded the improved speed of set. It appears that the Examiner has admitted that adding a sulfonamide compound results in an improved speed of set relative to a composition without such a sulfonamide compound. Applicants submit that this could not have been expected from the cited documents, especially in view of the fact that Eckhardt et al. describe that the compounds cited by the Examiner are used as inert diluents. Thus, one of skill in the art would not have been motivated to use any sulfonamide, particularly one with an SO₂-NH group, as presently claimed.

Further, the presently recited compound having an SO₂-NH group is not inert (as Eckhardt et al.’s diluent is explicitly described) for at least the reason that it enhances setting speed. Even further, an advantage obtained by selecting a relatively small concentration of the compound having an SO₂-NH group (e.g., enhanced setting speed) is not disclosed in Eckhardt et al. Moreover, one of skill in the art would not even expect to obtain such an advantage because an inert component (e.g., an inert diluent) would generally not enhance setting speed or affect setting speed whatsoever.

Further, it should be noted that increasing the concentration of the compound having an SO₂-NH group would tend to decrease viscosity, which would not be desired for a dental composition. A less viscous composition would be difficult to apply to, for example, teeth of the upper jaw. Further, as the amount of the compound having an SO₂-NH group increases, the component may tend to act as a diluent. Thus, Eckhardt et al.’s disclosure of an inert diluent at least implies that the amount of the inert diluent is higher than the presently recited amount of the compound having an SO₂-NH group.

Further, there is no teaching or suggestion of any advantage provided by the claimed compounds in Eckhardt et al. For at least the reason that incorporating a compound having an SO₂-NH group (as presently recited) into the polyether-containing composition enhances the setting speed, the amides used are not inert in the sense they are described by Eckhardt et al. (at paragraph [0049], it is stated “esters or amides of alkylsulphonic acid and arylsulphonic acids used as inert diluent” (emphasis added)). An inert diluent typically does not have any effect on the setting speed.

The Examiner also alleged, “Applicant has admitted that amides of alkylsulfonic acids and arylsulfonic acids would encompass the instant species, and thus there would be no dispute that the instant compound with SO₂-NHR group would be an obvious variation of the amides taught by Eckhardt et al.” (Office Action dated September 25, 2009, page 3.) Applicants disagree. Even assuming *arguendo* that Applicants stated that Eckhardt et al.’s phrase “amides of alkylsulphonic acid and arylsulphonic acids” (paragraph [0049]) includes a number of compound classes, Applicants have not admitted that the compounds recited in the present claims are obvious in light of Eckhardt et al.’s disclosure. Given the number of variables which must be selected, the nature and significance of the differences between Eckhardt et al. and the present claims, and given the unpredictable nature of the technology, Applicants submit that the enhanced setting speeds (see table above) would not be obvious to one of ordinary skill in the art. Eckhardt et al. have provided no guidance to aid one of skill in the art to choose any particular amides of alkylsulfonic acids and arylsulfonic acids, much less the presently recited compounds.

In order to obtain this advantage (shorter working time; more rapid curing) Eckhardt et al. suggest adding an antacid-acting compound selected from the group of oxides, hydroxides . . . (see, for example, paragraphs [0023] and [0036]). This, however, is a completely different class of materials. There is no suggestion or motivation for the skilled person to focus on the amides claimed in the present invention.

As discussed herein above, Applicants submit that Eckhardt et al. fail to provide a suggestion or motivation for the skilled person to choose the particular compounds having an

SO₂-NH group recited in independent claims 1 and 11-14. Applicants further submit that Eckhardt et al. also fail to direct one of skill in the art to further select the recited amounts of a compound having an SO₂-NH group in the dental compositions (and kits and methods) recited in claims 1 and 11-14 (i.e., about 0.01% by weight to about 6.0% by weight).

Applicants' position is supported by the decision of the Federal Circuit in *In re Baird*, 29 USPQ2d 1550 (1994), and, after *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (2007), the rationale used by the Federal Circuit in *In re Baird* was reiterated in *Ortho-McNeil Pharm., Inc. v. Mylan Labs. Inc.*, 86 USPQ2d 1196 (Fed. Cir. 2008). The Federal Circuit reiterated that a claim cannot be rendered obvious by a prior disclosure that includes several unpredictable alternatives without some guidance to select features recited in the claim. The Federal Circuit contrasted a situation as presented in *KSR* (e.g., "a situation with a finite, and in the context of the art, small or easily traversed, number of options;" 86 USPQ2d at 1201) with situations in which the path to the claimed subject matter is less direct. The Federal Circuit rejected the argument, based on language from *KSR*, that claims to a new drug were obvious in light of "a finite number of identified, predictable solutions." *Id.* The Federal Circuit noted that one skilled in the art, even if provided with a general class of compound from which to start, would not necessarily have chosen the starting compound selected by the patentee. *Id.*

In the present application, the teachings of Eckhardt et al. describe innumerable combinations of compounds and amounts thereof, but provide no guidance to select a compound having an SO₂-NH group in the recited amounts.

Without guidance that directs one of ordinary skill in the art to a compound having an SO₂-NH group in an amount of about 0.01% by weight to about 6.0% by weight, the recitation of "inert diluents" and the general teaching of 0 to 95 wt. % does not render Applicants' claims obvious. Eckhardt et al. describe innumerable combinations of compounds and amounts thereof, but provide no guidance to select Applicants' recited compound in the recited amounts. Consequently, the obviousness analysis with respect to Applicants' claims is similar to the analysis by the Federal Circuit in *Ortho-McNeil* (a post-*KSR* case). Applicants respectfully

submit that the presently pending claims are not obvious in view of Eckhardt et al. Applicants therefore respectfully request notification to this effect.

“[A] reference that ‘teaches away’ from a given combination may negate a motivation to modify the prior art to meet the claimed invention. . . . A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” *Ormco Corp. v. Align Tech. Inc.*, 79 U.S.P.Q.2d 1931, 1938 (Fed. Cir. 2006).

The Examiner has failed to properly consider the portions of Eckhardt et al. in which the compounds cited by the Examiner are described as inert. As mentioned above, an inert diluent would generally not enhance early setting speed. The Examiner appeared to ignore the explicit disclosure of Eckhardt et al. that the diluents used are inert or has impermissibly picked and chosen from Eckhardt et al. only that which supports the obviousness rejection without consideration of the document as a whole. The Examiner alleged that “how one call the same compound is immaterial since one can be his own lexicographer.” (Office Action dated February 2, 2010, page 3.) Applicants submit that while Applicants (not a cited document) can be their own lexicographers (M.P.E.P. § 2111.01), the Examiner may not ignore a cited document’s disclosure. Rather, Applicants reiterate that “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” M.P.E.P. §2141.02(VI) (citing *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)) (emphasis in original).

The Examiner has also failed to properly consider the portions of Eckhardt et al. in which the compounds cited by the Examiner are described as diluents. As mentioned above, increasing the concentration of Eckhardt et al.’s inert diluent would generally decrease the viscosity of Eckhardt et al.’s composition. Such a decrease in viscosity would be disadvantageous for a dental composition when, for example, applying the composition to the teeth of the upper jaw.

Serial No.: 10/564,102

Confirmation No.: 7195

Filed: June 19, 2006

For: DENTAL COMPOSITION COMPRISING ETHYLENE IMINE COMPOUNDS AND NON-REACTIVE ACCELERATORS

For at least this reason, Eckhardt et al.'s characterization of this component as a diluent at least implies that the concentration of the component is not within the presently recited concentration range. Applicants submit that the Examiner must consider these portions of Eckhardt et al. that would lead away from the claimed invention. *See* M.P.E.P. §2141.02(VI).

Schmitt et al. (cited for disclosure of an initiator) do not provide that which is missing from Eckhardt et al.

Applicants submit that the cited documents, when considered in their entirety (as is required), fail to provide adequate support for the present obviousness rejections and actually teach away from Applicants' claims.

Reconsideration and withdrawal of the rejections of claims 1-3, 7-15, 17, 19, 21, 23, and 25 are requested.

B. Claims 1-3, 7-11, and 13-15 are not unpatentable under 35 U.S.C. §103(a) as being unpatentable over Zech et al. (U.S. Patent No. 6,894,144 or WO 01/17483).

Without acquiescing to the Examiner's rejection or supporting allegations and merely to expedite prosecution of the present application, claims 1, 11, 13, and 14 have been amended and now recite a dental composition (e.g., claim 1), a kit (e.g., claim 11), a method of producing a dental composition (e.g., claim 13), and a method for enhancing the setting speed of a dental composition (e.g., claim 14), each of which include, among other things, a compound having an SO₂-NH group (e.g., SO₂-NHR or SO₂-NH₂), wherein the compound is present in an amount of about 0.01% by weight to about 6.0% by weight.

Insofar as this rejection applies to the presently pending claims, it is respectfully traversed.

In the present rejection, the Examiner relied on Zech et al.'s disclosure of constituents of catalyst components that include 0 to 95 weight percent (preferably 10 to 90 weight percent, and particularly preferably 40 to 85 weight percent, relative to the overall weight of the catalyst component or the base component (column 5, line 44 to column 6, line 19)) of at least one inert

diluent. The Examiner has apparently equated Zech et al.'s inert diluent to the presently recited compound having an SO₂-NH group and alleged that Zech et al.'s amounts of the diluents overlaps the instant amounts ("about 0.01% by weight to about 6.0% by weight") of the compound having an SO₂-NH group.

"[I]t is not uncommon that a 'species' may be patentable, that is, satisfy sections 101-103, notwithstanding a prior art 'genus.'" *In re Ornitz*, 376 F.2d 330, 336, 153 USPQ 453, 458 (CCPA 1967). "The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a prima facie case of obviousness." M.P.E.P. §2144.08 (citing *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)). Furthermore, "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." M.P.E.P. §2141.02 (citing *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)) (emphasis in original).

Applicants submit that the Examiner committed clear error by failing to consider Zech et al. as a whole and, thus, by failing to acknowledge that mere overlap of the amounts of a compound does not establish a *prima facie* case of obviousness, especially when that compound is not explicitly disclosed or suggested by Zech et al.

"The *KSR* Court recognized that '[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.' *KSR*, 127 S. Ct. at 1732." *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 1739 (2008) (emphasis added). Applicants submit that what Zech et al. disclose "clearly is not the easily traversed, small and finite number of alternatives that *KSR* suggested might support an inference of obviousness." See *Ortho-McNeil Pharm. Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008).

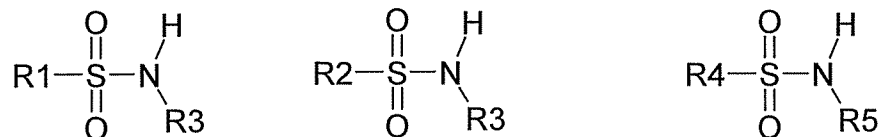
For example, from the very broad range of concentrations (0 to 95 weight percent, preferably 10 to 90 weight percent, and particularly preferably 40 to 85 weight percent, relative

to the overall weight of the catalyst component or the base component (column 5, line 44 to column 6, line 19)) of inert diluent disclosed by Zech et al., one of skill in the art would be required to select a relatively small concentration in a relatively narrow range ("about 0.01% by weight to about 6.0% by weight") to arrive at the presently claimed concentration. Applicants' recited range of weight percentage is a very small fraction of the range disclosed in Zech et al. and falls outside of Zech et al.'s diverging preferred and particularly preferred ranges. Further, Zech et al. provide no motivation to select an amount within the recited concentration range (about 0.1% by weight to about 6.0% by weight).

In addition to a selection of the presently recited amounts of the compound having an SO₂-NH group, Applicants submit that one of ordinary skill in the art must make a number of other selections to arrive at the presently claimed dental compositions, kits, and methods. Thus, the Examiner has not established a *prima facie* case of obviousness of the present claims over Zech et al.

As discussed hereinbelow and in Applicants' remarks at pages 11-18 of Applicants' Amendment and Response submitted December 14, 2009, incorporated herein by reference, Applicants submit that Zech et al. do not disclose or suggest the presently recited compound having an SO₂-NH group. Thus, the alleged overlap in the amounts of the recited compound having an SO₂-NH group and Zech et al.'s inert diluent is irrelevant. Thus, the Examiner's reliance thereon in support of the present obviousness rejection is clear error.

As currently claimed, each of the independent claims incorporates a compound having an SO₂-NH group, wherein the compound is represented by at least one of the following formulas:



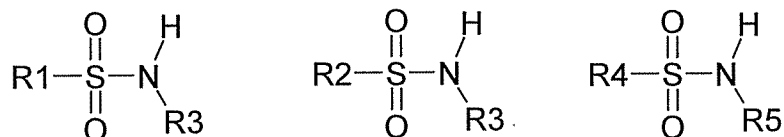
wherein R1-R5 are as recited in the claims and wherein the compound is present in an amount of about 0.01% by weight to about 6.0% by weight. Zech et al. do not disclose a dental

composition (or kit or method) including about 0.01% by weight to about 6.0% by weight of an SO₂-NH group-containing component as recited in the present claims.

Zech et al. also fail to specify the amides which might be used as their so-called inert diluents. Also, there is no disclosure in Zech et al. that the amides have to include an SO₂-NH group, as presently claimed. Zech et al.'s phrase "amides of alkylsulphonic acids and arylsulphonic acids" (column 6, lines 14-15) does not comprise only amides having an SO₂-NHR group (as presently claimed) or an SO₂-NH₂ group (as presently claimed), but also amides comprising an SO₂-NR₂ group (not presently claimed), wherein R is different from H.

Zech et al. are totally silent regarding whether the inert diluent is a compound having a SO₂-NH group. In evaluating lack of disclosure regarding an obviousness rejection, the Court of Customs and Patent Appeals stated that "[s]ilence in a reference is hardly a proper substitute for an adequate disclosure of facts from which a conclusion of obviousness may justifiably follow." *In re Burt and Walter*, 148 U.S.P.Q. 548, 553 (C.C.P.A. 1966).

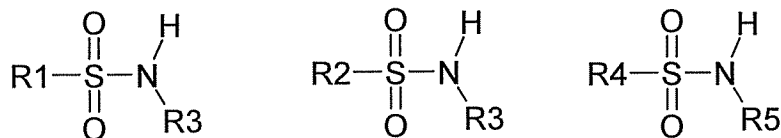
Thus, in order to arrive at the claimed subject matter, the person skilled in the art has to make the following selections: (1) identify from the group of possible compounds suggested as inert diluents the esters or amides of alkylsulfonic acids and arylsulfonic acids; (2) select the amides and not the esters of said acids; (3) select the compounds represented by at least one of the following formulas:



and (4) select each of groups R1-R5 as presently claimed (e.g., wherein R1 is a moiety selected from the group consisting of C₁-C₂₂ alkyl, C₂-C₂₂ alkenyl, C₂-C₂₂ alkynyl, C₇-C₂₂ arylalkyl and C₃-C₂₂ cycloalkyl, wherein one or more hydrogen atoms of the moiety may be replaced by Cl or F and/or up to five carbon atoms may be replaced by atoms or group of atoms selected from O, CO, N, and S, R2 is a moiety selected from the group consisting of C₆-C₁₈ aryl, C₇-C₂₂ alkylaryl, C₂-C₂₂ cycloalkylaryl, C₇-C₂₂ alkenylaryl and C₇-C₂₂ alkynylaryl, wherein one or more hydrogen

atoms of the moiety may be replaced by Cl or F and up to five carbon atoms may be replaced by atoms or group of atoms selected from O, CO, N, and S, R3 is H, R1, or R2, R4 is R1 or R2, and R5 is a chemical linkage to a polymer).

Even further, Applicants' Representatives have not located and the Examiner has not identified any blaze marks in the cited documents that would lead one of skill in the art down a path to select all of the subject matter of the present claims. Thus, Applicants request that the Examiner point to the blaze marks in the cited documents, either explicit or implicit, or anywhere in the general knowledge of one of skill in the art, that would lead one of skill in the art down a path to select, for example, a dental composition (or kit or method) that includes a compound having an SO₂-NH group, wherein the compound is represented by at least one of the following formulas:



wherein R1-R5 are as defined in the claims and wherein the compound having an SO₂-NH group is present in an amount of about 0.01% by weight to about 6.0% by weight (e.g., claim 1).

Applicants have found that selecting particular amounts of a compound having an SO₂-NH group provides advantages for the presently claimed dental compositions (or kits or methods). In a dental setting, it is not only desired to have a dental composition that hardens to a particular hardness, but it is also frequently desired to enhance setting speed. That is, early setting of the dental composition is frequently desired to reduce the time required for a dental procedure, thereby enhancing the patient's experience. Applicants have found that by selecting, for example, the recited amounts of a compound having an SO₂-NH group of "about 0.01% by weight to about 6.0% by weight" (e.g., amended claims 1, 11, 13, and 14), the setting speed can be enhanced. In particular, dental compositions having increased 6-, 8-, and 10-minute Shore A Hardnesses provide a significant advantage over alternative compositions, even if the ultimate Shore A Hardnesses (e.g., measured at 15 or more minutes) may be similar.

Such advantage obtained by selecting the recited amounts of the recited compound having an SO₂-NH group is not disclosed or suggested in Zech et al.

By using the particular recited substances, Applicants have observed that the speed of set can be improved (that is, providing a dental composition with a shorter working time). Experimental evidence of this effect (showing that sulfonamides with an SO₂-NRR' (R = alkyl, R' = alkyl) group do not accelerate the speed of cure in the same manner as sulfonamides with an SO₂-NHR group, as shown in the Specification at Table 6, Entry 13, or sulfonamides with an SO₂-NH₂ group, as shown in the Specification at Table 6, Entry 14) was submitted in the Declaration of Dr. Thomas Klettke on July 14, 2009.

Applicants note that the speed of set varies from compound to compound. Where an early high Shore Hardness A is desired, Applicants have found that the compound used in Entry 15 (SO₂-NR₂) is less effective than, for example, the compounds in Entry 13 (SO₂-NH₂) and Entry 14 (SO₂-NHR), as is evident in the following table.

Entry	Compound	Shore A Hardness after 6 min	Shore A Hardness after 8 min	Shore A Hardness after 10 min
15	SO ₂ -NR ₂	23	33	37
14	SO ₂ -NH ₂	33	40	42
13	SO ₂ -NHR	30	37	42

(See Applicants' specification at pages 19 and 20.)

The Examiner alleged that the scope of the claims is broader than the showing in the Declaration of Dr. Thomas Klettke. (Office Action dated September 25, 2009, page 3.)

Although this is true, the experimental data in the Declaration establish that Zech et al.'s mere disclosure of the phrase, "amides of alkylsulphonic acids and arylsulphonic acids" used as inert diluent, does not necessarily disclose or suggest the subject matter of the present claims.

Applicants submit that the dental compositions (and kits and methods) of the present claims offer

enhanced setting speeds and that Zech et al. fail to offer any guidance to one of skill in the art to select the presently recited components and form a composition or kit therewith.

While the Examiner appeared to focus on the Shore A Hardnesses of Entries 13-15 after 15 minutes (Office Action dated February 2, 2010, pages 3-4), Applicants submit that the Examiner has failed to properly consider the evidence submitted by Applicants traversing the present rejections; namely, early setting (e.g., increased Shore A Hardness values at 6, 8, and 10 minutes) of the presently claimed dental compositions (and kits and methods).

Applicants respectfully remind the Examiner that “[e]vidence traversing rejections . . . must be considered by the examiner whenever present.” M.P.E.P. §716.01.

Applicants are unclear as to the Examiner’s intent at page 4 of the Office Action dated February 2, 2010, where the Examiner noted that all of the simplest form of the compound (such as having SO₂-NH₂, SO₂-NHR, or SO₂-NR₂) yielded the improved speed of set. It appears that the Examiner has admitted that adding a sulfonamide compound results in an improved speed of set relative to a composition without such a sulfonamide compound. Applicants submit that this could not have been expected from the cited documents, especially in view of the fact that Zech et al. describe that the compounds cited by the Examiner are used as inert diluents. Thus, one of skill in the art would not have been motivated to use any sulfonamide, particularly one with an SO₂-NH group, as presently claimed.

Further, the presently recited compound having an SO₂-NH group is not inert (as Zech et al.’s diluent is explicitly described) for at least the reason that it enhances setting speed. Even further, an advantage obtained by selecting a relatively small concentration of the compound having an SO₂-NH group (e.g., enhanced setting speed) is not disclosed in Zech et al. Moreover, one of skill in the art would not even expect to obtain such an advantage because an inert component (e.g., an inert diluent) would generally not enhance setting speed or affect setting speed whatsoever.

Further, it should be noted that increasing the concentration of the compound having an SO₂-NH group would tend to decrease viscosity, which would not be desired for a dental

composition. A less viscous composition would be difficult to apply to, for example, teeth of the upper jaw. Further, as the amount of the compound having an SO₂-NH group increases, the component may tend to act as a diluent. Thus, Zech et al.'s disclosure of an inert diluent at least implies that the amount of the inert diluent is higher than the presently recited amount of the compound having an SO₂-NH group.

Further, there is no teaching or suggestion of any advantage provided by the claimed compounds in Zech et al. For at least the reason that incorporating a compound having an SO₂-NH group (as presently recited) into the polyether-containing composition enhances the setting speed, the amides used are not inert in the sense they are described by Zech et al. (at column 6, lines 6-15, it is stated, "There can be used, as inert diluents . . . esters or amides of alkylsulphonic acids and arylsulphonic acids" (emphasis added)). An inert diluent typically does not have any effect on the setting speed.

Even assuming *arguendo* that Applicants stated that Zech et al.'s phrase "esters or amides of alkylsulphonic acids and arylsulphonic acids" (column 6, lines 6-15) includes a number of compound classes, Applicants have not admitted that the compounds recited in the present claims are obvious in light of Zech et al.'s disclosure. Given the number of variables which must be selected, the nature and significance of the differences between Zech et al. and the present claims, and given the unpredictable nature of the technology, Applicants submit that the enhanced setting speeds (see table above) would not be obvious to one of ordinary skill in the art. Zech et al. have provided no guidance to aid one of skill in the art to choose any particular amides of alkylsulfonic acids and arylsulfonic acids, much less the presently recited compounds. There is no suggestion or motivation for the skilled person to focus on the amides claimed in the present invention.

As discussed herein above, Applicants submit that Zech et al. fail to provide a suggestion or motivation for the skilled person to choose the particular compounds having an SO₂-NH group recited in independent claims 1, 11, 13, and 14. Applicants further submit that Zech et al. also fail to direct one of skill in the art to further select the recited amounts of a compound

having an SO₂-NH group in the dental compositions (and kits and methods) recited in claims 1, 11, 13, and 14 (i.e., about 0.01% by weight to about 6.0% by weight).

Applicants' position is supported by the decision of the Federal Circuit in *In re Baird*, 29 USPQ2d 1550 (1994), and, after *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (2007), the rationale used by the Federal Circuit in *In re Baird* was reiterated in *Ortho-McNeil Pharm., Inc. v. Mylan Labs. Inc.*, 86 USPQ2d 1196 (Fed. Cir. 2008). The Federal Circuit reiterated that a claim cannot be rendered obvious by a prior disclosure that includes several unpredictable alternatives without some guidance to select features recited in the claim. The Federal Circuit contrasted a situation as presented in *KSR* (e.g., "a situation with a finite, and in the context of the art, small or easily traversed, number of options;" 86 USPQ2d at 1201) with situations in which the path to the claimed subject matter is less direct. The Federal Circuit rejected the argument, based on language from *KSR*, that claims to a new drug were obvious in light of "a finite number of identified, predictable solutions." *Id.* The Federal Circuit noted that one skilled in the art, even if provided with a general class of compound from which to start, would not necessarily have chosen the starting compound selected by the patentee. *Id.*

In the present application, the teachings of Zech et al. describe innumerable combinations of compounds and amounts thereof, but provide no guidance to select a compound having an SO₂-NH group in the recited amounts.

Without guidance that directs one of ordinary skill in the art to a compound having an SO₂-NH group in an amount of about 0.01% by weight to about 6.0% by weight, the recitation of "inert diluents" and the general teaching of 0 to 95 wt. % does not render Applicants' claims obvious. Zech et al. describe innumerable combinations of compounds and amounts thereof, but provide no guidance to select Applicants' recited compound in the recited amounts. Consequently, the obviousness analysis with respect to Applicants' claims is similar to the analysis by the Federal Circuit in *Ortho-McNeil* (a post-*KSR* case). Applicants respectfully submit that the presently pending claims are not obvious in view of Zech et al. Applicants therefore respectfully request notification to this effect.

“[A] reference that ‘teaches away’ from a given combination may negate a motivation to modify the prior art to meet the claimed invention. . . . A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” *Ormco Corp. v. Align Technology Inc.*, 79 U.S.P.Q.2d 1931, 1938 (Fed. Cir. 2006).

The Examiner has failed to properly consider the portions of Zech et al. in which the compounds cited by the Examiner are described as inert. As mentioned above, an inert diluent would generally not enhance early setting speed. The Examiner appeared to ignore the explicit disclosure of Zech et al. that the diluents used are inert or has impermissibly picked and chosen from Zech et al. only that which supports the obviousness rejection without consideration of the document as a whole. The Examiner alleged that “how one call the same compound is immaterial since one can be his own lexicographer.” (Office Action dated February 2, 2010, page 3.) Applicants submit that while Applicants (not a cited document) can be their own lexicographers (M.P.E.P. § 2111.01), the Examiner may not ignore a cited document’s disclosure. Rather, Applicants reiterate that “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” M.P.E.P. §2141.02(VI) (citing *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)) (emphasis in original).

Applicants also submit that Zech et al.’s disclosure of 0 to 95 weight percent, preferably 10 to 90 weight percent, and particularly preferably 40 to 85 weight percent, relative to the overall weight of the catalyst component or the base component (column 5, line 44 to column 6, line 19) of at least one inert diluent actually teach away from the relatively low concentrations in the present claims (“about 0.01% by weight to about 6.0% by weight”). The concentrations disclosed by Zech et al. diverge from those claimed. Applicants reiterate that “[a] reference may be said to teach away when a person of ordinary skill, upon reading the reference, . . . would be

led in a direction divergent from the path that was taken by the applicant.” *Ormco Corp. v. Align Tech. Inc.*, 79 U.S.P.Q.2d 1931, 1938 (Fed. Cir. 2006).

The Examiner has also failed to properly consider the portions of Zech et al. in which the compounds cited by the Examiner are described as diluents. As mentioned above, increasing the concentration of Zech et al.’s inert diluent would generally decrease the viscosity of Zech et al.’s composition. Such a decrease in viscosity would be disadvantageous for a dental composition when, for example, applying the composition to the teeth of the upper jaw. For at least this reason, Zech et al.’s characterization of this component as a diluent at least implies that the concentration of the component is not within the presently recited concentration range. Applicants submit that the Examiner must consider these portions of Zech et al. that would lead away from the claimed invention. *See* M.P.E.P. §2141.02(VI).

Applicants submit that the cited documents, when considered in their entirety (as is required), fail to provide adequate support for the present obviousness rejections and actually teach away from Applicants’ claims.

Reconsideration and withdrawal of the rejections of claims 1-3, 7-11, and 13-15 are requested.

C. Claims 1-3, 7-11, 13-15, 17, 19, 23, and 25 are not unpatentable under 35 U.S.C. §103 over Zech et al. (U.S. Patent No. 6,894,144 or WO 01/17483) in view of Schmitt et al. (U.S. Patent No. 4,167,618).

Applicants submit that the presently rejected claims are not unpatentable for at least the reasons provided hereinabove regarding the rejection of claims 1-3, 7-11 and 13-15 under 35 U.S.C. §103 over Zech et al.

Schmitt et al. (cited for disclosure of an initiator) do not provide that which is missing from Zech et al.

Reconsideration and withdrawal of the rejections of claims 1-3, 7-11, 13-15, 17, 19, 23, and 25 are requested.

New Claims

New claims 26 and 27 are patentable for at least the reasons provided herein above and by reason of their own respective recitations. In particular, the cited documents fail to disclose the dental composition of claim 1 wherein the Shore Hardness A measured after 6 minutes according to DIN EN ISO 53505 is greater than (e.g., claim 26) (e.g., more than 30% greater than (claim 27)) a value measured for the dental composition without component (b) as it is defined in claim 1.

New claims 28 and 29 are patentable for at least the reasons provided herein above and at pages 11-19 of Applicants' Amendment and Response submitted December 14, 2009.

Applicants submit that the cited documents fail to disclose or suggest a dental composition including, among other things, a compound having an SO₂-NH group wherein such compound is selected from the group consisting of benzene sulfonic acid N-butyl amide, p-toluene sulfonic acid N-ethyl amide, o-toluene sulfonic acid N-ethyl amide, benzene sulfonic acid amide and a mixture of o-/p- toluene sulfonic acid N-ethyl amide (e.g., claim 28) or wherein such compound comprises p-toluene sulfonic acid N-ethyl amide (e.g., claim 29).

New claims 30-34 are patentable for at least the reasons provided herein above and by reason of their own respective recitations. In particular, the cited documents fail to disclose the dental composition of claim 1, kits of claims 11 and 12, or methods of claims 13 and 14, wherein R3 is R1 or R2.

Prompt notification of the allowance of claims 26-34 is requested.

Amendment and Response

Page 36 of 36

Serial No.: 10/564,102

Confirmation No.: 7195

Filed: June 19, 2006

For: DENTAL COMPOSITION COMPRISING ETHYLENE IMINE COMPOUNDS AND NON-REACTIVE ACCELERATORS

Summary

It is respectfully submitted that all of the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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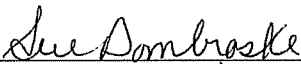
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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop **Amendment**, P.O. Box 1450, Alexandria, VA 22313-1450, on this 3rd day of May, 2010.

By: 
Name: Sue Dombroske
